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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,892	08/20/2001	Ronald Beck	1212 WO/US	5960

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EXAMINER
JOHNSTON, PHILLIP A

ART UNIT	PAPER NUMBER
2881	

DATE MAILED: 04/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/913,892	Applicant(s) BECK, RONALD
	Examiner Phillip A Johnston	Art Unit 2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *4-14 and 18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Claims Objection

1. Claims 4-14, and 18-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, Claims 4-14, and 18-20 have not been treated on the merits.

Claims Rejection – 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,494,824 to Apple, in view of Reich, U.S. Patent No. 6,425,174 and in further view of Gleason, U.S. Patent No. 5,032,719.

Regarding Claims 1-10 and 12-17, Apple (824) discloses a radiotherapy source vial in which radioactive fluid container 701 is inside an outer shield 720 and loaded into the injection apparatus 751 (FIG. 58). The outer shield 720 is typically made of

lead for protection during handling and use and provides both a safe shipping container as well as shielding for the operator during treatment. The outer shield 720 includes a proximal end cap 746 that is removed for loading of the radioactive fluid container 701. The end cap 746 is press-fitted into the outer shield 720 to provide additional shielding to aid in creating a close fit within a carriage 725, as recited in Claim 2. The end cap 746 includes an opening 722 through which the external control mechanism 706 is inserted for engagement with radioactive fluid seal 702. The opposite end of the outer shield 720 includes a second opening 721 through which the needle cannula 734 accesses the septum 707 of the radioactive fluid container 701. See Column 24, line 30-46, and Figure 56.

Apple (824) also discloses medical radiation treatment device 14 of FIG. 1 including a sealed, gas-tight container 15 with a gas-tight plunger 18 or gas-tight plunger base positioned opposite the distal end thereof for pushing radioactive fluid 12 from interior volume 17 of the container when as valve 13 is operated to the open position. The gas-tight valve can be a separate component that is attachable to the container or can be integrated into the container. This embodiment of sealed container 15 provides for a much more complete evacuation of the radioactive fluid in interior volume 17. In addition, the container walls can have varying degrees of glass/plastic radiation shielding for alternating higher radiation activity levels. See Column 9, line 59-67, and Column 10, line 1-13.

Regarding Claims 9 and 13, Apple (824) teaches the use of attachment mechanisms 727 for maintaining the radioactive fluid seal 702 in the initial position 813

for maintaining the initial volume 716 of radioactive fluid in the radioactive fluid container 701 during shipping and up until time of deployment. FIG. 65 is a partially sectioned side view of a radioactive fluid container 701 wherein the container end cap 742 has a pair of slots 777 therethrough that align with, and engage a pair of protuberances 776 located on the underside proximal end 818 of the radioactive fluid seal 702. The container end cap 742 is rotatable relative the radioactive fluid container 701. The slots, shown in FIG. 66, each have an enlarged end 823 and a narrowed end 822. The protuberances 776 each have an enlarged terminal portion 824 such that they engage the container end cap 742 when the protuberances 776 are aligned with the enlarged ends 823 of the slots and lock with the container end cap 742 when the vial end cap 742 is rotated counter-clockwise. When the external control mechanism 706 (engagement means recited in Claims 9,10 and 13) fully engages the engagement mechanism 704 of the radioactive fluid seal 702, it can rotate clockwise to align the protuberances 776 with the enlarged ends 823 of the slots 777 and disengage the locking mechanism 739. See Column 25, line 65-67, and Column 26, line 1-21.

Apple (824) as applied above does not disclose the use of a fourth container forming at least part of storage and/or transporting means for the further containers, as recited in Claim 12. However, Reich (174) discloses a method for transporting a syringe containing radioactive material to a location for use and, thereafter, to a disposal area. The method begins with the insertion of a housing into a lower portion of a radiopharmaceutical pig. The syringe is then inserted into the housing. Next, the

radiopharmaceutical pig is assembled by securing an upper portion to the lower portion, so that the radiopharmaceutical pig contains the syringe and the housing in an inner chamber. After the radiopharmaceutical pig is assembled, it is transported to the location for use. At the location, the radiopharmaceutical pig is disassembled by removing the upper portion from the lower portion. When the radiopharmaceutical pig is disassembled, the inner chamber is accessible for removal of the syringe from the housing. The transportation container includes a radiopharmaceutical pig having an outer shell made of relatively stronger ABS plastic. Another more detailed feature of the invention, the housing is transparent, thereby advantageously enabling the user to view a contaminated syringe without risk. See Column 3, line 48-62, and Column 5, line 23-28.

Therefore it would have been obvious to one of ordinary skill in the art that Apples' (824) radiotherapy source vial can be modified to use the transportation container in accordance with Reich, if so desired.

Regarding Claims 11 and 18, the utilization of materials that will allow containers of radioactive substances to be autoclavable, is well known in the art. For example see U.S. Patent No.'s 5,739,004; 6,204,505; and 6,531,705.

It is implied herein that the shielding means of Apple (824) would be removed to make radiation measurements of the radioactive substance, as recited in Claim 14.

Regarding Claims 19 and 20, Apple (824) discloses the use of a number of dispensing mechanism's in Figures 47-50, wherein the container is retained in upright and upside down positions; however, Apple (824) does not disclose the use of a

casing suspended on a pivot axis. Gleason (719); discloses a receptacle generally designated by the numeral 10, the removable cover generally designated by the numeral 12, the vertically movable source carrier rod generally designated by the numeral 14, and the radiation source carrier rod locking and positioning assembly generally designated by the numeral 16. Also shown is the pivotable handle 22, which is mounted upon the receptacle 10. see Column 3, line 51-60.

Therefore it would have been obvious to one of ordinary skill in the art that Apples' (824) radiotherapy source vial can be modified to use the pivotable handle in accordance with Gleason , to provide a design that is inherently safe and simple to use.

Conclusion

4. Any inquiry concerning this communication or earlier communications should be directed to Phillip Johnston whose telephone number is (703) 305-7022. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor John Lee can be reached at (703) 308-4116. The fax phone numbers are (703) 872-9318 for regular response activity, and (703) 872-9319 for after-final responses. In addition the customer service fax number is (703) 872- 9317.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0956.

PJ

March 24, 2003

JOHN R. LEE
SUPERVISORY PATENT EXAMINER
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